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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,448	07/08/2003	Jeffry G. Weers	0103.11	1036
21968	7590	08/19/2005	EXAMINER	
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,448	<b>Applicant(s)</b> WEERS ET AL.	
	<b>Examiner</b> Edward J. Webman	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al in view of Vaghefi.

Edwards et al disclose delivery of phospholipids matrix-containing particles with a mass mean diameter between 5 and 30 microns and a tap (bulk) density of 0.4g/cm<sup>3</sup> which together yield an aerodynamic diameter of the particles between 1 and 5 microns for use in a method of administration employing a passive dry powder inhaler (see abstract, lines 3-9, p. 6 lines 2-13, p. 8 lines 11-21, p. 9 lines 12-13, p. 11 lines 23-27, and p. 33 lines 23-29). Any agent can be incorporated (page 20 line 1-page 21 line 14). Over 35 % of particles are considered respirable (page 34 lines 12-14). DPPC is specified (page 6 line 1). Enhanced delivery is disclosed (page 5 lines 24-25). The dry powder inhaler SPINHALER is specified (page 33 line 26). Edwards et al do not teach the passive dry particle inhalers ECLIPSE, TURBOSPIN, ROTOHALER and FLOWCAPS. Nor do Edwards et al teach budesonide.

Applicants stipulate that ECLIPSE, TURBOSPIN, ROTOHALER and FLOWCAPS are passive dry inhalers of commerce, as indicated by the fact that they are registered trademarks (page 19 lines 23-25).

It would have been obvious to one of ordinary skill to deliver antibiotics using the method of Edwards et al in a passive dry powder inhaler of commerce to achieve the

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beneficial effect of enhanced delivery. As to the claimed budesonide, Vaghefi teaches that it is deliverable by dry powder inhaler (column 12 line 10). Thus, one of ordinary skill would deliver budesonide with the inhalation method of Edwards in view of its deliverability as an inhaled powder as taught by Vaghefi. As to applicants' claimed properties, it is argued that the stipulated passive dry powder inhalers of commerce in combination with the disclosed particles in Edwards et al provide the same delivery properties as claimed. Applicants have shown no criticality for the claimed budesonide as opposed to other actives.

Applicants argue that Edwards et al do not teach the now claimed resistance and emitted dose for claimed flow rates. However, applicants disclose PDIs which are items of commerce. Therefore, it is argued that the now claimed properties must be possessed by these items of commerce.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**EDWARD J. WEBMAN  
PRIMARY EXAMINER  
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